

Remarks

Claims 1-18 are pending and are under examination.

A 1.132 Declaration by Applicant is submitted herewith, as well as accompanying documents.

Examiner does not address or ascertain the level of ordinary skill in the pertinent art as required under MPEP 2141.

Response to Rejection of Claims 1-18 under 103(a), obviousness

The Examiner has rejected claims 1-18 as allegedly obvious over Harris (dated 1998, but no publication information provided) in view of Risley (U.S. Patent No. 7,198,045).

Applicant traverses the rejection for the reasons described below. First, Applicant will demonstrate that neither reference can be cited as prior art against the present application (see item "I" below). Second, Applicant will provide arguments as to why, even assuming arguendo that either reference could be cited as prior art, the two references do not render the present claims obvious (see item "II" below).

Applicant further provides a § 1.132 Declaration with exhibits to address the Harris reference.

I. Harris and Risley are Improper Prior Art

A. Harris is not a printed publication or public document

Examiner has cited Harris as prior art, but provides no basis for that use. Harris was submitted anonymously with a letter dated June 1, 2005 containing an anonymous statement that it was a printed publication circulated in 1998. The anonymous letter indicated that the same was sent to Applicant. Applicant did indeed receive a similar letter anonymously and upon receipt did call Examiner to discuss the content. It was received and discussed with the Examiner well before the current Office Action was issued. However, Examiner provides no basis for use of the Harris document as prior art.

Applicant asserts that Harris (a clinical proposal written by the present Applicant) is not a prior art reference under the conditions set forth in 35 U.S.C. § 102 and therefore cannot be relied upon as a prior art reference under 35 U.S.C. § 103 for the reasons set forth below.

The statements in the anonymous letter are incorrect regarding the Harris document being a printed publication that was circulated and Applicant asserts that the person submitting such a statement is either not aware of the laws governing prior art or purposely made a false statement.

Applicant asserts that the cited Harris reference is a research proposal submitted by Applicant for consideration by the Medical College of Virginia and its Institutional Review Board, and was **never** a printed publication or a document available publicly and therefore does not qualify under 35 U.S.C. § 102 as a prior art reference and cannot be used in a 103 rejection. Applicant is submitting a 1.132 Declaration with this Response to further validate and verify that the Harris document was never a printed publication or publicly known. Nowhere in the case law or in the MPEP is such a document considered prior art.

When Applicant was a student at the Medical College of Virginia, the Harris document cited by the Examiner was written by Applicant and submitted in confidence to the Medical College of Virginia for review as part of an application for a clinical research study. Such proposals are considered by the Institutional Review Board (“IRB”) for the university and are always confidential. In fact, the term “proposal” is used throughout the Harris document. Applicant further provides supporting documents with the 1.132 Declaration to verify that such proposals are confidential and that they are not even available to the public under the Freedom of Information Act. The face/cover page of the Harris document verifies the name of the Applicant (Michael Harris), that the document applicant classification was a “Medical Student Principal Investigator”, and that the institution was the Medical College of Virginia. The contents of the document provide further evidence that it was merely a proposal, because it provides no data, and refers to confidentiality and the IRB. Additionally, provided with the 1.132 Declaration is the copy of an Opinion (Exhibit 2; Opinion 01-101) of the Attorney General of the state of Virginia stating that such documents are confidential and are not even available to the public via the Freedom of Information Act.

Therefore, Applicant respectfully submits that the use of Harris is not proper and requests that the Examiner withdraw the use of the Harris reference.

Because Harris is not a proper prior art reference, the obviousness rejection of Harris in view of Risley fails for that reason.

B. Risley is not a proper prior art reference

Applicant asserts that Risley is not a prior art reference under the conditions set forth in 35 U.S.C. § 102 and therefore cannot be relied upon as a prior art reference under 35 U.S.C. § 103 for the reasons set forth below.

Risley was filed Feb. 10, 2003, without benefit of priority of an earlier filed application. The present application under consideration was filed in the U.S. on September 12, 2003, and has the benefit of priority of PCT /US02/09416 filed on Monday, March 25, 2002 (March 23, being a Saturday), which has the benefit of priority of U.S. Provisional Patent Application No. 60/278,141, filed on March 23, 2001. Therefore, Risley cannot be cited against the present application. Therefore, because Risley does not have a proper filing or priority date which qualifies as prior art under 35 U.S.C. § 102, it cannot be used in a 103 rejection and the rejection of Harris in view of Risley fails for that reason.

C. Conclusion

Because neither Harris nor Risley are proper prior art references under 102, neither can be cited against the present application in a 103 rejection. Furthermore, even if one of the two cited references were a proper prior art reference, the rejection would fail because the two references could not be combined according to the rejection issued by the Examiner. Thus, the rejection fails either way.

For these reasons, Applicant submits that the obvious rejection as to claims 1-18 should be withdrawn and Applicant further submits that the claims are in condition for allowance.

II. Harris in view of Risley does not render claims 1-18 obvious

Although Applicant asserted above that neither the Harris document or Risley are proper prior art references, Applicant addresses the two references here as if, presuming *arguendo*, they did qualify as proper prior art.

Applicant notes that the Examiner does not address or ascertain the level of ordinary skill in the pertinent art as required under MPEP 2141 and requests that any further actions do so.

Examiner asserts that the Harris document discloses hyperbaric oxygenation for increasing a ratio of CD4/CD8 lymphocytes, reducing viral load (citing the Abstract and Narrative) and the use of nitric oxide gas. The Examiner asserts that the difference between Harris and claim 1 is the selecting one or more time-periods for exposing the patient to the selected gas(es) and pressure(s). The Examiner asserts that Risley in a hyperbaric chamber teaches time periods for patients in the hyperbaric chamber (col. 4, lines 48-57). The Examiner asserts that it would have been obvious for one of ordinary skill in the art at the time the invention was filed to select time periods as taught by Risley. The Examiner further asserts it

would be have been obvious that no set time period or gas pressure for everyone would work the same, as different people have different needs (i.e., young vs. old), and that a health care provider would take each patient and evaluate their needs to set up a treatment schedule for time and pressure in the hyperbaric chamber, and that the remaining steps would have been obvious from the use of the hyperbaric chamber of Harris/Risley.

Regarding claim 2, Examiner asserts that Harris discloses other gases (citing the Narrative).

Regarding claim 3, Examiner asserts that Harris does not specifically state wherein one or more pressures selected is greater than one atmosphere, however it would be inherent that the pressure would be greater than one atmosphere because the device is a hyperbaric chamber.

Regarding claims 4-6, the Examiner notes the rejection of claim 1.

Regarding claim 7, the Examiner admits that Harris does not disclose the step of creating a chart for the person with listing of times and gas based upon the patient's condition, and then asserts that one of ordinary skill in the art would consider the step obvious if not inherent, in order for a medical person to note progress or the condition of the patient getting worse a chart would be made for each person based upon their needs to have time and gas treatment set up by the medical practitioner.

Regarding claim 8, the Examiner asserts that Risley teaches a hyperbaric chamber large enough for more than one person (citing Col. 3, lines 60-67). The Examiner then concludes that it would have been obvious to one of ordinary skill in the art to have more than one person in the chamber as such chambers are well known in the art as taught by Risley.

Regarding claim 9, the Examiner refers to the rejection of claim 1.

Regarding claim 10, the Examiner refers to the rejection of claim 1 and states that it would have been obvious to one of ordinary skill in the art to arrive at the percentage of gases in the chamber based upon haw many patients are in the chamber and their medical conditions requiring treatment.

Regarding claims 15-18, the Examiner refers to the rejections of claims 1 and 10 above.

Applicant traverses the obviousness rejection for the following reasons:

Preliminarily, the three-prong test which must be met for a reference or a combination of references to establish a *prima facie* case of obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142.

Additionally, MPEP § 2143.01 provides: “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).” However, the “teaching, suggestion, motivation” test (“TSM”) must not be rigidly applied (*KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007)), but to determine whether there is an apparent reason to combine the known elements in the fashion as claimed, the analysis should be made explicit by the Examiner (*Id*).

None of these criteria have been met here.

Additionally, MPEP 2143.02 requires that there be at least some degree of predictability for there to be a reasonable expectation of success (*In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). Because Harris was merely a proposal with no data, the hypothesis posited therein was no more than a wish and a hope and could not possibly have had any level of predictability as to imparting a reasonable expectation of success if it were combined with Risley. That predictability must be determined at the time the invention was made (*Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).

The present application is the first to disclose that the use of inhaled nitrogen is effective in treating viral infection. Claim 1 of the present application recites:

1. A method for increasing a ratio of CD4/CD8 lymphocytes, reducing a viral load and restoring an immune system, including lymph node architecture, of a person infected with at least one virus, such as HIV, wherein the person is placed in a hyperbaric chamber and exposed to one or more gases at one or more atmospheric pressures for one or more time-periods, the method comprising the steps of: selecting the one or more gases to be used in the hyperbaric chamber; selecting the one or more pressures to be used in the hyperbaric chamber; selecting the one or more time-periods that the patient is exposed to the selected gas(es) and pressure(s) while in the hyperbaric chamber; placing the patient in, or having the patient enter, the hyperbaric chamber wherein monitoring of the patient's vital signs may optionally be provided; and, exposing the patient to the

selected one or more gases, at the selected one or more pressures for the selected one or more time-periods.

Applicant asserts that Harris does not teach the elements of claim 1 or its dependent claims as asserted by the Examiner. First, the cited Harris reference was merely a clinical research proposal, provided no data, and the discussion therein was a mere wish and a hope, and provided no reason or motivation for one of ordinary skill in the art to combine it with another reference and arrive at the claims of the present invention. Because the Harris document provides no data or details of the proposed experimentation in the proposal, Applicant further asserts that the Harris document is not an enabling disclosure and thus cannot be used as a prior art reference against the present application. Furthermore, the disclosure therein reciting other studies teaches away from the present invention.

On page 3, in the item 1 entitled “1. Nitrogen narcosis” it is taught that hyperbaric N₂ at increasing pressures, as seen in deep sea divers, actually has detrimental effects on the divers. This would not motivate one of ordinary skill in the art to use hyperbaric N₂ to arrive at the presently claimed invention as recited in claim 1 and its dependent claims, and in fact teaches away from the invention as claimed. Further evidence that the Harris reference proposal was merely a wish and a hope is presented at page 3 in the text and graph at the bottom of the page under the section entitled “2. Anesthetic membrane effects:” In that section, the last two sentences of the page states:

“Shinomiya et al. (1994) found a strong correlation of depth of dive and suppression of CD4 cell counts (Fig. 1). These authors (p. 217) suggested “rapid changes in hydrostatic pressure or psychological stress, which lead [sic] to unbalanced production of hormone/cytokine to account for their findings”

The graph, which follows the statements at the bottom of page 3 of Harris, shows that with increasing pressure/depth, the CD4/CD8 ratio decreases in the subjects. This teaching in Harris is in direct conflict with what is claimed in the present application, i.e., as in claim 1 “A method for increasing a ratio of CD4/CD8 lymphocytes, reducing a viral load and restoring an immune system, including lymph node architecture, of a person infected with at least one virus, such as HIV, wherein the person is placed in a hyperbaric chamber and exposed to one or more gases at one or more atmospheric pressures. . .”. Based on the teachings in Harris related to item

1 and item 2 described above, no one of ordinary skill in the art would have had a reason or motivation to modify the teachings of Harris, or to combine the teachings of Harris with another reference such as Risley, and would have no reasonable expectation of success. In fact, Harris taught away. Furthermore, even if Harris and Risley were combined using those teachings, the result would be the exact opposite of what is recited in claim 1 and its dependent claims.

Regarding Risley, it in fact merely teaches the use of a hyperbaric chamber for treatment of pain using low pressure (see abstract) and there would be no motivation or reason to combine a method for treating pain with one for treating a disease. Risley does not teach, suggest or contemplate any of these elements: a method for increasing a ratio of CD4/CD8 lymphocytes; reducing a viral load and restoring an immune system; including lymph node architecture; of a person infected with at least one virus; such as HIV; use of a pressurized chamber to cause an atom, molecule or compound into an attachment site on a cell wall of a living cell or into a receptor unit on the virus, whereby the atom, molecule, or compound prevents the virus from replicating by preventing the virus from attaching to the attachment of the living cell; the use of nitrogen; blocking virus attachment to host cells; preventing virus replication in a host; and restoring a patient's immune system; as recited in independent claims 1, 9, and 15. Furthermore, the low pressure taught by Risley (less than 32.0 inches of Hg, is only slightly higher than about 1 atm (1 atm = 760 mm Hg = 29.9 in. Hg), is less than the higher pressure recited in independent claims 1 and 15 and their dependent claims, but lower than that of independent claim 9 and its dependent claims, which do not recite the use of a hyperbaric chamber or increased pressure using a hyperbaric chamber. Therefore, there would no reason or motivation to combine Risley with Harris or a reasonable expectation of success as to claims 1-18, because it teaches different amounts of pressure than the claims as recited.

Contrary to the Assertion of the Examiner, neither Harris nor Risley teach, suggest, or even contemplate each and every element of independent claim 15 and its dependent claims 16, 17, and 18. As admitted by the Examiner Harris and Risley teach the use of hyperbaric chambers. However claims 15, 16, 17, and 18 do not recite the use of hyperbaric chambers. Claim 15 recites:

15. A method for the treatment of patients infected with a virus, including HIV, involving the inhalation of nitrous oxide at normal atmospheric pressure wherein inhaled nitrogen blocks virus-host attachment sites and prevents the virus from replicating thereby reducing viral load and restoring a patient's immune

system, the method comprising the steps of: selecting an inhalation period, wherein the patient inhales gases comprising nitrous oxide during the inhalation period; selecting a number of times to repeat the inhalation period; having the patient inhale the gases comprising nitrous oxide for the selected inhalation period and, repeating the step of having the patient inhale the gases for the selected number of times.

Therefore, neither Harris nor Risley, teach or suggest each and every limitation of claim 15 and its dependent claims. In fact, even if the teachings of Harris and Risley were combined, they do not result in the present invention as recited in claims 15-18.

Regarding the Examiner's comments about "health care providers", as recited on page 3, or "medical person", as recited on page 3, or "inherent" as recited on pages 3 and 4 of the Office Action, Applicant asserts that the Examiner provides no evidence that health care providers/medical person would have known or done what the Examiner speculates they would have done nor evidence of inherent indications for use, and that the Examiner should provide evidence of such to indicate that Examiner is not using impermissible hindsight or taking notice to arrive at such a conclusion. For example, the Examiner states that as to claim 3, it would be "inherent" to increase pressure because it is a hyperbaric chamber. However, applicant notes that no one was using a hyperbaric at that time to treat viral infections, therefore it would not have been inherent to do so because it would not have even been obvious to do so, and Applicant further notes that the mere fact that a hyperbaric chamber is being used does not mean that there must be pressure as well.

Presuming *arguendo* that the references show the elements or concepts urged by the examiner, the examiner has presented no line of reasoning, and we know of none, as to why the artisan viewing only the collective teachings of the references would have found it obvious to selectively pick and choose various elements and/or concepts from the several references relied upon to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (PTO Bd App. 1985); *In Re Horn*, 203 USPQ 969 (CCPA 1979). The collection of references supports the inescapable conclusion that the Examiner has pieced the references together to support a rejection on the basis of hindsight.

As the Federal Circuit has held numerous times, however, such a hindsight analysis is impermissible -- instead, the Examiner must show suggestions, explicit or otherwise, that would compel one of ordinary skill to combine the cited references in order to make and use the

claimed invention. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) (“When prior art references require selective combination by the [fact-finder] to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.”); *Fine*, 5 USPQ2d at 1600 (“One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”); *In re Pleuddemann*, 910 F.2d 823, 828 (Fed. Cir. 1990) (noting that use of an applicant’s specification as though it were prior art to support an obviousness determination is legal error); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (holding that both the suggestion to combine references, and a reasonable expectation of success in making the claimed invention, “must be founded in the prior art, not in the applicant’s disclosure.”). The Board has also provided the same mandate on this issue:

"it is impermissible to use the claimed invention as an instruction manual or “template” to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious a rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis."

Ex parte Haymond, 41 USPQ2d 1217, 1220 (Bd. Pat. App. Int. 1996). Thus, the use of hindsight analysis in the present case is impermissible and cannot be used to attempt to establish a *prima facie* case of obviousness.

Accordingly, if the scope and content of the cited prior art are properly considered as set forth above, it becomes clear that the combination of the Harris and the Risley patent do not lead the ordinary skilled artisan to Applicants' presently-claimed invention as set forth in claims 1-18.

Conclusion

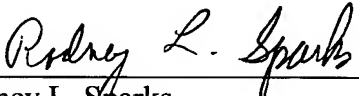
For the reasons described above, not only are the cited references of Harris and Risley improperly cited as prior art, their combination would not have been obvious, nor does that combination result in the present invention as claimed. Therefore, Applicants requests that the

103 rejection as to Harris and Risley be withdrawn and submits that the claims are in condition for allowance.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (434) 243-6103.

Respectfully submitted,

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